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10/580,753	11/30/2006	Alex Duggan	252805	8872

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
04/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,753	DUGGAN ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/26/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *17-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept **under PCT Rule 13.1.**

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 23-24, drawn to a composition for nasal or buccal application.

Group II, claim(s) 17-20, drawn to a method of preparing a composition for nasal or buccal application.

Group III, claim 21, drawn to a method of delivering an active agent to the nose or throat.

** Claim 22 is a “use claim” and can not be classified under any group at this time. In the event that the claim is amended to any one of the above statuses, it will be joined at that time.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical feature in all groups is a composition for nasal or buccal application. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Gaubert et al teach antigen delivery using Spherulites^{TM}, which can be delivered to the nasal passage.

A telephone call was made to Mr. Kenneth Spina on 04/01/10 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

--In the instant specification, at least (h), BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S) is missing.

--The use of the trademarks such as Spherulites™ have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. See MPEP 608.01(v).

--The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

--The Latin names of botanical species should be italicized.

-- Claims contain improper capitalization of certain chemicals, species, actives, excipients, etc.

-- Independent claims begin with the article "A" and dependent claims begin with the article “The”.

--Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See MPEP § 608.01(m).

Claim 13 is objected to for containing a period in line 3.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they are not legible. Especially it is not possible to determine what is being disclosed in Figure 2/2. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8, 10, 13 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recites “or the like”, “etc”, “derivatives” and “extracts”. Claim 24 recites an active agent effective in reduction of snoring or apnea.

The specification discloses dosage forms such as oral ingestion, gargle, lozenge, and surfactants such as phospholipids. It also discloses pharmacological agents such as decongestants, anti-histamines which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) are directed to encompass substances which only correspond in some undefined way to specifically instantly limitations. Specification does not teach one of ordinary skill in the art what the scope of other e.g. dosage forms or active agents are and thus does not meet the written description provision of 35 USC § 112, first paragraph. Claims are drawn to limitations that are highly variant and encompass a myriad of possibilities. The specification provides no guidance to one of ordinary skill in the art as to how to determine elements which fulfill this description. The specification provides insufficient written description to support the genus encompassed by the claim.

Furthermore, with the exception of the above specifically disclosed elements, the skilled artisan cannot envision the broad scope of the encompassed derivatives, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Additionally, the instant invention is directed to **extracts** (e.g, calendula officinalis flower extracts, glycerine extracts, peppermint extract, etc) with the intended use of preparing compositions. The specification does not disclose any solvents that may be utilized to extract components, any method of extracting and does not indicate what

particular components are found in those extracts. The term “extracts” does not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are or composed of. The specification provides insufficient written description to support the genus encompassed by the claim. Note: MPEP §2163.

With regard to claim 24, while the specification discloses a composition comprising active ingredients effective in the reduction of snoring or apnea, specification fails to name any specific active ingredients and one of ordinary skill in the art would not have been able to determine what active ingredients would be suitable or that applicants had possession of such active ingredient at the time of invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:
The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Therefore, the claims do not meet the written description provision of 35 USC §

112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115).

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

****The claims are generally narrative and indefinite, **failing to conform with current U.S. practice.** They appear to be replete with grammatical and idiomatic errors. Corrections are required.

Claims 1-16 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims **2, 4-5, 8, 10 and 13-16** recite the broad recitation of “for example”, “eg”, “such as”, “including without limitation”, “ideally” and “in particular” which are to a narrower statement of the range/limitation.

Regarding claims **2, 4-5, 10, 14, 16**, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims **2 and 8**, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claims **2 and 8**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 2 is indefinite for containing an improper broadening of the base claim. Claim 1 requires a composition “for nasal and buccal application” and claim 2 recites “the composition of claim 1 in the form of an aerosolizable composition”. Then claim 2 recites the composition is administered by oral ingestion and also in the form of solids

such as pastille and lozenge. As claim1 is limited to nasal and buccal administration, oral ingestion is considered improper broadening of the base scope. Also a lozenge is NOT in an aerosolisable form.

Regarding claims 2 and 16, the word "means" is preceded by the word(s) "of spray" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

The term "good" in claim **3** is a relative term which renders the claim indefinite. The term "good" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term “good adhesion” has not been defined by the specification.

Claims 11-13 recite the limitation "the active ingredient" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1, which all of the said claims depend on, lacks disclosure of the term “active ingredient”.

Claim 14 recites the limitation "the liquid base" in 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 which the said claim depends on lacks disclosure of “liquid base”.

Claims 23 recites the limitation "a novel active microparticle" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 which the said claim depends on lacks disclosure on “active microparticle”.

Claim 6 is indefinite for reciting “particle levels are of 10-25% within the composition”. It is indefinite because it is not clear what applicants intended to claim by “levels”. It is also not clear what is meant by “within the composition”. Is it meant to be the concentration of microparticles based on the total composition?

Claims 5, 8, 11 and 13 are indefinite for employing parenthesis in the claims. It is indefinite because it is unclear whether the limitations enclosed within parentheses are part of the claimed invention. See MPEP § 608.01(m). In other words, contents of parentheses have no effect on the scope of the claims. Only reference characters can be enclosed within parentheses.

Claims 2, 8, 10, 11 and 13 are indefinite for reciting the alternative limitations in an improper format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity. See MPEP § 2173.05(h) for guidance.

Claim 15 is indefinite for reciting “additional active ingredients” with regard to composition of claim 1. Claim 1 does not recite any actives, thus claim 15 can not comprise additional active ingredients.

Claim 16 is indefinite for reciting “to a subject in use”. It is not clear how the subject (i.e. patient) can be in use.

Claim 9 is indefinite for reciting "comprising hydrophilic and hydrophobic agents". It is unclear if the composition comprises hydrophilic and hydrophobic agents in addition to active agents, surfactants and polar medium or if the applicants meant that the active agents may be hydrophilic or hydrophobic.

Claim 10 is indefinite for reciting "active ingredients with other activities". It is not clear what the other activities are. This is not claim language under U.S. practice.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 23 is rejected under 35 U.S.C. 101 because claim 23 is drawn to microparticles that are commercially available (as stated by Specification, page 9 and Gaubert et al). Thus it has been shown that claim 23 is not an invention or discovery of a new composition or process.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaubert et al (XP-002342759).

Gaubert et al teach antigen delivery using Spherulites™, which can be delivered to the nasal passage.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Applicant's own admission.

Applicant recites, in their specification, that multilayer microparticles are known and commercially available e.g. Spherulite (Capsulis SA). The particle size is 0.1 to 10 micron (se page 9, lines 8-10)

Claims 1-2, 4-5, 8, 12, 14-16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Radhakrishnan et al (5,192,528).

Radhakrishnan et al teach an aqueous suspension of sized liposomes containing a drug in liposome-entrapped form which is aerosolized under conditions which produce aerosol particle sizes favoring particle deposition in a selected region of the respiratory tract. Radhakrishnana et al also teach a method of delivering a therapeutic dosage of corticosteroid drugs to the lung (see abstract). Radhakrishnan et al teach the particle size distribution and teach what particle size is suitable for each target site in respiratory

tract. Particles are sized below 10 microns (see col. 6, lines 21-37). The method of forming an aqueous liposome suspension is described in columns 4 and 5, indicating suitable active agents, the lipid components such as phospholipids. The formulations are delivered to patients respiratory system by way of devices such as nebulizers (col. 9, lines 10-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talton et al (6,984,404).

Talton et al teach coated drug particles and pharmaceutical formulations thereof. The coating techniques described and the pharmaceutical compositions derived therefrom are applicable to a wide variety of drugs delivered to the lungs, such as anti-asthmatic drugs, as well as orally administered and parenteral administered drug particles as well. The oral drug is formulated with a thin-film coating of the present invention. Exemplary pharmaceuticals that would benefit from such a coating include drugs used in controlled or targeted release formulation, taste-masking, or particulate surface modification prior to tableting or capsule filling (see col. 6, lines 13-45). The coated particles may have a size range of from 0.1 micron to 1000 microns (col. 8, lines 40-68).

Talton et al disclose that the particles may comprise excipients such as lubricants, buffers, binders, sweetening agents and carriers. The formulations may contain at least about 1% of the active agent. The active may comprise up to 70% of the formulation. The oral formulation may be in the form of a mouthwash, oral spray, buccal

tablet, dentrifrice, sublingual formulation, pastes, powders, gels, etc, and the formulations may comprise water, foaming agents, etc. (see col. 10, lines 58).

Talton et al disclose that by carrier they mean all solvents, dispersion media, vehicles, diluents, carrier solutions, suspensions, etc. Talton et al also teach the administration of the said formulations for nasal delivery of active agents (col. 12, lines 12-50). Medicaments which may be coated and administered in aerosol formulations include theophylline, ephedrine, phenylephrine and the like (col. 13, lines 11-58). The materials used in the preparation of coating compositions include polymers, polysaccharides and proteins (col. 14, lines 6-36).

Talton et al disclose that encapsulation of glucocorticosteroids into liposomes can lead to the enhancement of therapeutic efficacy, with a reduction in their toxicity and prolongation of their therapeutic effect (col. 22, lines 52-60).

While Talton et al do not anticipate the formulations as claimed such as the details of claim 9, it provides sufficient teachings to one of ordinary skill in the art to make and use the invention as claimed. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to have implemented the teachings of Talton et al in preparing multilayered microparticles comprising active agents for delivery to the nose or buccal cavity because it is disclosed that such particles provide for controlled release, reduce side effects and toxicity of active agents and improves the efficacy of drug delivery. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements

as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **11-16 and 23-24** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 21 of copending Application No. 11/570,493 (US 20070218114). Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims would have been obvious over the instant claims. Instant claims are to a composition comprising active agents distributed in a base. The formulation may be in a form for nasal or oral delivery. The reference claims are also drawn to a composition comprising active agents distributed in a base material. The formulation may be for oral delivery.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616